

REMARKS

Claims 1-15 currently appear in this application, claims 4-15 have been withdrawn. The Office Action of December 4, 2007, has been carefully studied. These claims define novel and unobvious subject matter under Sections 102 and 103 of 35 U.S.C., and therefore should be allowed. Applicant respectfully requests favorable reconsideration, entry of the present amendment, and formal allowance of the claims.

Rejections under 35 U.S.C. 112

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner alleges that failure to specifically identify the trisubstituted triazines and agents makes the claims indefinite.

This rejection is respectfully traversed. Claim 1 has been amended to recite that the triazines and other compounds interact with prohibition or mitochondrial ATPase. Among these compounds are oligomycin and aurovertins. As noted on page 14, lines 1-4, one skilled in the art, without undue experimentation, can readily determine compounds that

interact or bind with mitochondrial ATPase using conventional techniques.

It should be noted that the method claimed herein is a method for determining if a compound is a compound that stimulates pigmentation or one that inhibits pigmentation. It is not necessary to list the specific compounds, as one skilled in the art can readily determine if the compounds may interact with or bind mitochondrial ATPase. Once one has identified a compound that may bind with or inhibit ATPase, one uses the herein claimed test to determine if the compound affects pigmentation. It is respectfully submitted that the method claimed is definite. The method involves the following steps:

- a. measuring the amount of melanin or tyrosinase in cells or extracts of cells;
- b. treating the cells with a compound to be tested (i.e., the test compound);
- c. determining the amount of melanin or tyrosinase in the treated cells or extracts of cells;
- d. noting if there is a change in the amount of melanin or tyrosinase in the cells or the extract of cells in the presence of the test compound as compared to the cells or extract of cells in the absence of the test compound. If

there is a change in the amount of melanin or tyrosinase in the cells or extract of cells treated with the test compound, this indicates that the compound affects pigmentation.

The Federal Circuit has emphasized that "[t]he test for indefiniteness does not depend on a potential infringer's ability to ascertain the nature of its own product but instead on whether the claim delineates to a skilled artisan the bounds of the invention." *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1340 (Fed. Cir. 2005). In the present case, one skilled in the art can readily follow the steps of the method to determine if a compound affects melanin, and whether the compound, if it affects melanin production, increases or inhibits melanin production.

#### **Art Rejections**

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mars et al., *Pigment Cell Research*, 1995, **Volume 8, issue 4** 194-201.

This rejection is respectfully traversed. The Examiner concedes that Mars does not disclose the steps of the herein claimed screening method for testing compounds specifically for pigmentation. Although Mars shows that trithiocyanuric acid, a trisubstituted triazine compound, has

melanin-affinic properties, this has nothing at all to do with the herein claimed method. Mars has nothing to do with determining if a compound inhibits or increases pigmentation, and merely notes that trithiocyanuric acid has melanin-affinic properties. There is no suggestion in Mars of identifying pigment-affecting compounds by testing the compounds in the presence of cells or cell extracts. Mars is looking for compounds that will target melanoma so that melanoma-destroying drugs can be delivered directly to the melanoma.

Mars uses screening methods to identify possible melanoma seekers. The presently claimed method is directed to determining if a compound affects melanin production, and, if so, whether the compound inhibits or increase melanin production. The herein claimed method provides a screening for compounds suspected of affecting melanin activity, and has nothing to do with the Mars method of screening for possible melanoma seekers.

In view of the above, it is respectfully submitted that the claims are now in condition for allowance, and favorable action thereon is earnestly solicited.

Appln. No. 10/821,981  
Amd. dated May 5, 2008  
Reply to Office Action of December 4, 2007

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.  
Attorneys for Applicant

By: /Anne M. Kornbau/  
Anne M. Kornbau  
Registration No. 25,884

AMK:srd  
Telephone No.: (202) 628-5197  
Facsimile No.: (202) 737-3528  
G:\BN\N\NYUM\ORLOW 1A\pto\2008-05-05Amendment.doc